



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JAN 10 2007

Food and Drug Administration  
Rockville MD 20857

Re: Rozerem  
Docket No. 2006E-0040

The Honorable Jon Dudas  
Under Secretary of Commerce for Intellectual Property and  
Director of the United States Patent and Trademark Office  
Box Patent Extension  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Director Dudas:

This is in regard to the patent term extension application for U.S. Patent No. 6,034,239 filed by Takeda Pharmaceutical Company, Ltd., under 35 U.S.C. § 156. The patent claims Rozerem (ramelteon), NDA 21-782.

In the June 19, 2006, issue of the Federal Register (71 Fed. Reg. 35274), the Food and Drug Administration published its determination of this product's regulatory review period, as required under 35 U.S.C. § 156(d)(2)(A). The notice provided that on or before December 17, 2006, 180 days after the publication of the determination, any interested person could file a petition with FDA under 35 U.S.C. § 156(d)(2)(B)(i) for a determination of whether the patent term extension applicant acted with due diligence during the regulatory review period.

The 180-day period for filing a due diligence petition pursuant to this notice has expired and FDA has received no such petition. Therefore, FDA considers the regulatory review period determination to be final.

Please let me know if we can provide further assistance.

Sincerely yours,

Jane A. Axelrad  
Associate Director for Policy  
Center for Drug Evaluation and Research

cc: Mark Chao, Ph.D., J.D.  
Takeda Pharmaceuticals North America, Inc.  
475 Half Day Rd.  
Lincolnshire, IL 60069